Attorney Docket No. 06148.0026-03000

APPENDIX

Page 1, replace the paragraph beginning on line 4 (as amended in the Divisional Application Request filed on April 12, 2001) with the following new paragraph:

--This application is a [division] divisional of application Serial No. 09/105,068, filed June 26, 1998, [still pending,] which is a division of Serial No. 08/809,404, filed March 21, 1997, which is a 371 of PCT/US95/12894, filed October 5, 1995, which claims priority to Serial No. 60/003,415, filed September 8, 1995, now abandoned, and Serial No. 08/319,615, filed October 7, 1994, [abandoned] now abandoned, which is a continuation-in-part of 08/053,076, filed April 26, 1993, now abandoned.[, which is a continuation-in-part of 07/909,097, filed July 2, 1992, now U.S. Patent No. 5,583,454, which is a continuation of 07/600,753, filed October 9, 1990, now abandoned all of which are incorporated herein by reference.]--

Page 14, replace the paragraph beginning on line 2 with the following new paragraph:

--Referring to Figs. [2] 2A and 2B, an overview of operation of one preferred embodiment of the system according to the invention is illustrated. Prior to a particular procedure, the body elements which will be part of the procedure are scanned to determine their alignment, i.e., their pre-operative position. For example, the alignment may be such as illustrated in Fig. 3 wherein body elements 10, 20, and 30 are more or less aligned in parallel. These body elements may be bones or other rigid

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

bodies. In Fig. 3, three-dimensional skeletal elements 10, 20, 30 are depicted in two dimensions as highly stylized vertebral bodies, with square vertebra 11, 21, 31, small rectangular pedicles 12, 22, 32, and triangular spinous processes 13, 23, 33. During imaging, scans are taken at intervals through the body parts 10, 20, 30 as represented in Fig. 3 by nine straight lines generally referred to be reference character 40. At least one scan must be obtained through each of the body elements and the scans taken together constitute a three-dimensional pre-procedural image data set.--

Page 15, replace the paragraph beginning on line 33 with the following new paragraph:

--After imaging, the skeletal body elements 10, 20, 30 may move with respect to each other at the joints or fracture lines. In the procedure room, such as an operating room or a room where a medical procedure will be performed, after positioning the patient [the] <u>for</u> surgery, the body elements will assume a different geometry, such as the geometry depicted in Fig. 4.--

Page 16, replace the paragraph beginning on line 4 with the following new paragraph:

--As a result of this movement, the preprocedural image data set stored in memory 106, consisting of the scans through the skeletal elements, does not depict the operative position of the skeletal elements, as shown in Fig. 4. However, the shape of the skeletal elements, as depicted by the scans through the element, is consistent between imaging and procedure since they are rigid bodies, as indicated by the lines 40 through each element in Fig. 4. Therefore, the image data set must be modified to depict the intraprocedural geometry of the skeletal elements. This modification is

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

performed by identifying the location of each reference point of each skeletal element in procedure space. As diagrammatically illustrated in [Fig. 2] Figs. 2A and 2B, a localizer 108 (see Figure 13, below, for more details) identifies the location and provides this information so that the pre-procedural data set may be deformed or re-positioned into the displaced data set. As a result, the displaced data set is in registration with the intra-procedural position of the elements 10, 20, 30. Once the locations of the reference points are determined by the localizer 108, processor 104, which is a part of the work station, can execute software which re-positions the images of the skeletal elements to reflect the position of the actual elements in the procedure room thus forming the displaced set and the registration between the displaced set and the intra- procedural position.--

Page 17, replace the paragraph beginning on line 9 with the following new paragraph:

--Referring to [Fig. 2] Figs. 2A and 2B, an alternate preferred embodiment of the system according to the invention in the case where the body elements are not rigid, but rather semi-rigid such that shape deformations may occur to the body elements is described as follows. Prior to a particular procedure, the body elements which will be part of the procedure are scanned to determine their pre-operative position and shape. For example, the alignment may be such as illustrated in Fig. 3 wherein body elements 10, 20, and 30 are more or less aligned in parallel and have a defined shape. These body elements may be soft tissue such as the prostate or other semirigid bodies.--

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

Page 17, replace the paragraph beginning on line 22 with the following paragraph:

--After imaging, the elements 10, 20, 30 may move with respect to each other and also their shape may become deformed. In the procedure room, such as an operating room or a room where a medical procedure will be performed, after positioning the patient [the] <u>for</u> surgery, the body elements may assume a different geometry, such as the geometry depicted in Fig. 4 where geometry depicts both element alignment (position) and shape.--

Page 17, replace the paragraph beginning on line 30 with the following paragraph:

--As a result of this changed geometry, the pre-procedural image data set stared in memory 106, does not depict the operative geometry of the body elements, as shown in Fig. 4. Indeed, the shape of the body elements, as depicted by the scan through the element, may have changed between imaging and procedure since they are semi-rigid bodies. Therefore, the image data set must be modified to depict the current geometry of the body elements. This modification is performed by identifying the location of the reference points of each body element in procedure space. As diagrammatically illustrated in [Fig. 2] <u>Fig. 2B</u>, a localizer 108 <u>,</u>possibly in communication with a processor 104<u>,</u> identifies the location of the reference points and provides this information so that the preprocedural data set may be deformed into the displaced data set. Once the locations of the reference points are determined, processor 104, which is a part of the work station, can execute software which modifies the images of the body elements to reflect the geometry of the actual elements in the

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

B

procedure room thus forming the displaced set and the registration between the displaced set and the intra-procedural position. As a result, the, displaced data set is in registration with the intra-procedural geometry of the elements 10, 20, 30.--

Page 18, replace paragraph beginning on line 18 with the following new paragraph:

--According to one preferred embodiment of the invention, a reference frame 116 is attached to one of the body elements 10 at the beginning of the procedure. Various reference frame embodiments are illustrated in more detail in Figures 11 and [12] 11A - 11C and 12A - 12G, below. Reference frame 116 is equipped with a plurality of emitters 114 which together define a three-dimensional intraprocedural coordinate system with respect to the body element 10. In conventional terms, the reference frame 116 defines the stereotactic space with respect to the body element 10. Emitters 114 communicate with sensors 112 on a reference array 110 located in the pracerinre room and remote from the reference frame 116 and patient. If the body of the patient is not immobilized during surgery, then multiple reference frames may be required for each body element to define a surgical space with respect to each element. The surgical space may alternatively be defined by rigid fixation of the frame emitters 114 directly (or indirectly, for example, to the skin) to the skeletal elements 10, 20, or 30. In either case, the emitters 114 emit a signal which is received by the sensors 112. The received signal is digitized to compute position, for example, by triangulation. Through such information, the localizer 108 or a digitizer which is part of the localizer 108 can determine the exact three-dimensional position of the frame emitters 114 relative to the sensors 112. Thereby, localizer 108 or the processor 104 can exactly determine the

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

position of the reference frame 116 relative to the array which is free to move except during localization, e.g., activation of the emitters 114 on the reference frame 116 and activation of the probe emitters 112. Emitters 114 of the reference frame 116 are energized to provide radiation to the sensors 112, which radiation is received and gener ates signals provided to the localizer 108 for determining the position of the frame 116 relative to the array 110.--

Page 19, replace the paragraph beginning on line 19 with the following new paragraph:

--Next, it is necessary to determine the position of the body element 10, which may be a skeletal element, to which the reference frame 116 is affixed or positioned with respect to. In particular, the position of the body element 10 relative to the reference frame 116 must be determined, thereby determining the position of the body element 10 in the surgical space defined by the reference frame 116. After exposure of the reference points 10A, 10B, 10C by surgical dissection, the reference points are touched by the tip of a registration probe lie equipped with emitters 3-20. As each of the reference points 10A, 10B, 10C is touched by the tip of the probe 120, the emitters are energized to communicate with the sensors 112 of reference array 110. This communication permits the localizer 108 to determine the position of the registration probe 120, thereby determining the position of the tip of the probe 120, thereby determining the position of the reference point 10A on which the tip is positioned. By touching each of the reference points 10A, 10B, 10C on each body element 10, 20, 30 involved in the procedure, an intra-procedural geometry data is generated and stored in memory 121. This data is related to the corresponding

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

B

reference points on the pre-procedural images of the same elements by processor 104 which employs software to derive a transformation which allows the determination of the exact procedural position, orientation, and shape in surgical space of each body element, and thereby modifies the preprocedural image data set stored in memory 106 to produce a displaced image data set which is stored in memory [122] 123. The displaced image data set in memory [122] 123 reflects the geometry of the actual elements 10, 20, 30 during the procedure. Processor 104 displays the displaced image data set on display [124] 125 to provide a visual depiction of the geometry of the body elements 10, 20, 30 during the procedure. This image is used during the procedure to assist in the procedure. In addition, it is contemplated that an instrument, such as a forceps, a laser, a microscope, [a] an endoscope, or a radiation delivery system, which would be used during the procedure, may be modified by the addition of emitters. This modified device when moved into the area of the body elements 10, 20, 30 would be activated so that its emitters would communicate with the reference array 110 thereby permitting localizer 108 to determine the instrument's position. As a result, processor 104 would modify display 124 to indicate the position of the instrument, or the instruments focal point, such as by positioning a cursor, with respect to the body elements 10, 20, 30.--

Page 21, replace the paragraph beginning on line 16 with the following new paragraph:

--Reference frame 116 allows the patient to be moved during the procedure without the need for re-registering the position of each of the body elements 10, 20, 30. It is assumed that during the procedure, the body elements are fixed relative

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

B

to each other. Since the reference frame 116 is fixed (directly or indirectly) to body element 10, movement of the patient results in corresponding movement of the reference frame 116. Periodically, or after each movement of the patient, [array] <u>frame</u> emitters 114 may be energized to communicate with the sensors 112 of reference array 110 in order to permit localizer 108 to determine the position of the reference frame 116. Since the reference frame 116 is in a known relative position to element 110 and since we have assumed that elements 20 and 30 are in fixed relation to element 10, localizer 108 and/or processor 104 can determine the position of the elements and thereby maintain registration.--

Page 23, replace the paragraph beginning on line 26 with the following new paragraph.

--An ultrasound probe 128 equipped with at least three emitters 130 is then placed over the body element of interest. The contour (which ran be either two- or three-dimensional) of the body element is then obtained using the ultra-sound probe 128. This contour can be expressed directly or indirectly in the procedural coordinates defined by the reference system (surgical space). Emitters 130 communicate with sensors 112 of reference array 110 to indicate the position of the ultrasound probe 128. An ultrasound scanner [130] <u>166</u> which energizes probe 128 [determines] <u>to determine</u> the contour of the body element of interest [and] being scanned. This contour information is provided to processor 104 for storage in intra-procedural geometry data memory 121.--

Page 24, replace the paragraph beginning on line 4 with the following new paragraph:

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

--The intra-procedural contour stored in memory 121 is then compared by a contour matching algorithm to a corresponding contour extracted from the pre-operative image data set stored in memory 106. Alternatively, a pre-procedural contour data set may be stored in memory 134 based on a pre-procedural ultrasound scan which is input into memory 134 via scanner interface 102 prior to the procedure. This comparison process continues until a match is found for each one of the elements. Through this contour matching process, a registration is obtained between the images of each body element and the corresponding position of each element in the procedural space, thereby allowing the formation of the displaced image data set [122] 123 used for localization and display. Note that the contours used in the matching process only have to be sufficiently identical to accomplish a precise match - the contours do not have to be the same extent of the body element.--

Page 26, replace the paragraph beginning on line 34 with the following new paragraph:

--The above solutions achieve registration by the formation of a displaced image data set stored in memory [122] 123 which matches the displacement of the skeletal elements at the time of the procedure. An alternative technique to achieve registration is to ensure that the positions of the skeletal elements during the procedure are identical to that found at the time of imaging. This can be achieved by using a frame that adjusts and immobilizes the patient's position. In this technique, at least three markers are placed on the skin prior to imaging. These markers have to be detectible by the imaging technique employed and are called fiducials. A multiplicity of fiducials is desirable for improving accuracy. --

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

Page 29, replace the paragraph beginning on line 31 with the following new paragraph:

--Also connected via the break out box 118 is a reference frame assembly 120 including a reference frame 122 with cable connected to the break out box 118, a vertical support assembly 124, a head clamp attachment 126 and a horizontal support assembly [128] <u>129</u>. Optical probe [130] <u>164</u> (which is a localization frame) is also connected via cable to the digitizer control unit 114 via the break out box 118.--

Page 30, replace the paragraph beginning on line 3 with the following new paragraph:

--In operation, a patient's head (or other "rigid" body element) is affixed to the head clamp attachment [126] <u>127</u>. To determine the position of optical probe [130] <u>164</u> with respect to the head within the head clamp attachment [126] <u>127</u>, a surgeon would step on pedal 116 to energize the emitters of reference frame 122. The emitters would generate a light signal which would be picked up by camera array 110 and triangulated to determine the position of the head. The emitters of the optical probe 130 would also be energized to emit light signals which are picked up by the camera array to determine the position of the optical probe [130] <u>164</u>. Based on the relative position of the head and the probe [130] <u>164</u>, control box 114 would illustrate a preoperative scan on the screen of monitor 106 which would indicate the position of the probe relative to and/or within the head.--

Page 30, replace the paragraph beginning on line 35 with the following new paragraph:

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

--Either or both ends of the reference frame 122 may be provided with a bayonet fitting 144 for engaging a clamp which would also engage a Leyla retractor. One or both ends of the reference frame 122 is also formed into a radial projection 146 for supporting a screw 148 and crank handle 150 used to lock the reference frame to a head clamp such as head clamp [126] 127 shown in Fig. 11 or a Mayfield clamp. This allows the reference frame 122 to be placed in a fixed position relative to the head so that any movement of the head would also include corresponding movement of the reference frame 122.--

Page 31, replace the paragraph beginning on line 16 with the following new paragraph:

--Equally spaced about the reference frame 122 are a plurality of LEDs 152 for communicating with the camera array 110. The LEDs 152 are mounted in holes 154 in the upper base 134, which holes 154 are in communication with the cavity 140. Wires 156 are connected to each of the terminals of the LEDs 152 are positioned within the cavity 140. The other ends of the wires are connected to a connector 158 for engaging a cable connected to the digitizer 114 of the surgical navigation system. The cable provides signals for activating the LEDs 152. Connector 158 is mounted on a support projection 160 which projects from the base plate 136. This support projection 160 has a channel therein for permitting the wires to be connected to the connector 128. Fig. [11A] 11C is a wiring diagram of one preferred embodiment of the reference frame 122 according to the invention. As is illustrated in Fig. 11C, each LED terminal is connected to a separate pin of the connector 158. Although the invention is illustrated

09832840.072401

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

B

as having a connector for engaging a cable, it is contemplated that the reference frame 122 may be battery operated so that no cable is necessary.--

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000